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10/674,914

09/30/2003

Bevil J. Hogg

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EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,914

Applicant(s)

HOGG ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) 7, 18-22, 26, 31, 32, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-17, 23-25, 27-30, 33-35, 38-40 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Advisory Action dated 5/22/2007. The previous Final Action dated 1/19/2007 is hereby withdrawn and replaced with the action below, responsive to claims filed 10/16/2006. Claims 1, 23, 28, 33, and 38 are amended. Claims 49-53 are new. Claim 41 is cancelled. **Claims 1-6, 8-17, 23-25, 27-30, 33-35, 38-40, and 49-53** remain pending.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "57" in ¶0019 and "97" in ¶0021 of p.7 of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claim 53** is objected to because of the following informalities: It appears that claim 53 lacks completeness and the subject matter that the Applicant is claiming is indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-6, 8-9, 11-17, 23-25, 27-30, 33-35, 38-40, 49-51, and 53** are rejected under 35 U.S.C. 102(b) as being anticipated by Osadchy et al (US Pat No. 6266551).
6. In regard to **Claims 1 and 38**, Osadchy et al disclose a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body best seen in Figure 1 and 5, the system comprising:
- an elongate flexible medical device 20, together with an electronic identification device 90 that includes information on the physical and geometric properties of the elongate medical device, i.e. the position and orientation of distal tip 26 relative to coils as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29) for elongate flexible medical device identification (Col.17: 34-46);

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a navigation device 32 for actuating the distal end 26 of an elongate flexible medical device 20 and thereby changing its position/orientation (Col.10: 43-47);

an electronic interface 36 for selectively operating, i.e. allow or disallow operation of the navigation device (Col.17: 43-46) for selectively controlling the orientation of the distal end 26 of the elongate flexible medical device 20 (Col.19: 47-50), wherein the position of the distal end must also be necessarily determined for orientation control (Col.15: 65-68), the electronic interface comprising a processor 40 and inherently including at least one software program that enables navigation control only in the presence of the electronic identification device (Col.5: 60-62), wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device such as to allow or disallow operation, which instructions take into account the physical and geometric properties of the elongate medical device obtained from the electronic identification device, i.e. the position and orientation of distal tip 26 relative to coils as explained above.

7. In regard to **Claims 23, 28, and 33**, drafting a claim in Jepson format (i.e., the format described in 37 CFR 1.75(e); see MPEP § 608.01(m)) is taken as an implied admission that the subject matter of the preamble is the prior art work of another. In re Fout, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982).

8. Osadchy et al disclose a medical navigation for navigating the distal end of an elongate flexible medical device inside a subject's body, the system comprising an elongate flexible medical device 20; a navigation device 32 for actuating and orienting the distal end of the elongate medical device; an interface 36 comprising a processor 40

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and inherently at least one software program for selectively controlling the navigation device (Col.5: 54-62) to selectively orient the distal end of the elongate medical device (Col.19: 47-50), the improvement comprising an electronic identification device 90 provided with the elongate flexible medical device, which electronic identification device includes information on the physical and geometric properties of the elongate medical device, i.e. the position and orientation of distal tip 26 relative to coils as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), that the interface takes into account in providing actuation instructions to the navigation device for controlling the distal end 26 of the device, wherein the position of the distal end must be necessarily taken into account for navigational control (Col.15: 65-68), and further includes identification information that enables at least one navigation control software program of the interface to function (Col.17: 38-46).

9. In regard to **Claims 2, 25, 30, 35**, Osadchy et al disclose the electronic identification device 90 includes a memory (Col.16: 37-43), and wherein the interface 36 includes a reader for reading the memory (Col.16: 52-55).

10. In regard to **Claims 3, 27**, Osadchy et al disclose the electronic identification device 90 includes a memory unit (Col.16: 37-43) and a processing unit that communicates with the interface for transferring information (Col.7: 62-67).

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11. In regard to **Claims 4-5, 8-9, 40**, Osadchy et al disclose the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (Col.17: 33-46).

12. In regards to **Claim 6**, Osadchy et al disclose the electronic identification device 90 is a circuit, i.e. microcircuit best seen in Figure 5 that is connected to the interface 36.

13. In regards to **Claim 11**, Osadchy et al disclose the interface 36 inherently includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (Col.5: 50-62).

14. In regards to **Claim 12**, Osadchy et al disclose the electronic identification device 90 includes an integrated circuit.

15. In regards to **Claim 13**, Osadchy et al disclose the interface 36 operates on the electronic identification device 90 to prevent reuse of the elongate flexible medical device (Col.18: 46-55).

16. In regards to **Claim 14**, Osadchy et al disclose the interface 36 tracks elapsed time of use of the identified elongate flexible medical device 20 and invalidates use of the

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identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55).

17. In regards to **Claim 15**, Osadchy et al disclose the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device (Col.18: 9-55).

18. In regards to **Claim 16**, Osadchy et al disclose the electronic identification device 90 includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (Col.18: 9-55).

19. In regard to **Claims 17, 24, 29, 34, 39**, Osadchy et al disclose the at least one software program controls navigation by employing a computational model of flexible device physics related to the position and orientation of distal tip 26 relative to coils as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29) for elongate flexible medical device identification (Col.17: 34-46).

20. In regard to **Claims 49-50**, Osadchy et al disclose said information includes physical and geometrical properties unique to the device that are relevant and used in navigational control algorithms for guiding the device, the position and orientation of distal tip 26 relative to coils as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), wherein the position

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and orientation of the distal end are relevant and must be necessarily taken into account for navigational control (Col.15: 65-68).

21. In regards to **Claim 51**, Osadchy et al disclose the information including physical and geometric properties of the device includes at least one of the length of one or more flexible segments of the device, one or more cross-sectional areas of the device, and an elastic property of the device, wherein information regarding the distal tip of the catheter relative to coils necessarily includes the length of one ore more flexible segments of the device (Col.2: 64-67).

22. In regards to **Claim 53**, a complete search and rejection using prior art has not been made due to the incompleteness and indefiniteness of said claim.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Osadchy et al in view of Burnside et al (US Pat No. 6237604).

25. Osadchy et al disclose the electronic identification device 90 that transmit a signal to the interface 36 above but do not disclose said device is RF circuit. Burnside et al teach the use of an RF circuit to effectively transmit a signal (abst). Therefore, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to make the circuit of Osadchy et al a RF circuit as taught by Burnside et al as an effective means to transmit the signal to the interface.

26. **Claim 52** is rejected under 35 U.S.C. 103(a) as being unpatentable over Osadchy et al in view of Hall et al (US Pat No. 6428551).

27. Osadchy et al disclose the control system 32 for controlling the position and/or orientation of the distal end 26 of the elongate medical device 20 but do not disclose the control system is a magnetic navigation for controlling an elongate medical device that includes at least one magnet, nor said information includes physical properties of the elongate medical device including at least a magnet dimension or magnet type. However, Osadchy et al do disclose that said physical and geometric information can also relate to an actuator as well as information regarding the distal tip relative to coils (Col.19: 44-50).

28. Hall et al disclose an analogous elongate medical device comprising a magnet 36 that is controlled by a magnetic navigation system, best seen in Figure 2 (Col.6: 35-42) for more effective navigation. Hall et al also disclose that said magnet must be of sufficient size for the appropriate use (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the control system of Osadchy et al to use magnetic navigation to control the elongate medical device that includes at least one magnet, as taught by Hall et al, as a more effective means of navigation, and thereafter, have the information include physical properties of at least a magnet dimension or magnet type as relevant information pertaining to the

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actuator system of the elongate medical device as a proper calibration data, already taught by Osadchy et al above.

Response to Arguments

29. Applicant's arguments with respect to **Claims 1-6, 8-17, 23-25, 27-30, 33-35, 38-40, and 49-53** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340.


The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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